

Wisconsin Dept. of Agriculture, Trade and Consumer Protection Division of Agricultural Resource Management Bureau of Agrichemical Management

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NOTICE: Veterinary Feed Directive(s) Take Effect January 1, 2017

This document is for guidance purposes only and does not constitute legal advice. It is the responsibility of the commercial feed manufacturer/distributor to ensure they are in compliance with the applicable laws and requirements. Following the guidance in this document does not preclude regulatory or compliance action by the Wisconsin Department of Agriculture, Trade, and Consumer Protection, or any other regulatory agency, when authorized by local, state or Federal law, nor does it release any commercial feed manufacturer or distributor from legal responsibility or liability of any kind.

1. Did you file a Distributor Notice with FDA?

- (1) Send the notice prior to distribution or manufacture of any VFD feeds.
- (2) Write the company name, business address, an authorized agent's signature, date of signature, and "We plan to distribute Veterinary Feed Directive Feeds," on company letterhead and mail or fax to: Food and Drug Administration, Center for Veterinary Medicine, Division of Animal Feeds (HFV-220), 7519 Standish Place, Rockville, MD 20855 or fax to: 240-453-6882.

2. Have you checked FDA's website to find your name on the list?

(1) Do not distribute until your name is on the list. (Google "FDA, VFD Distributor List" – there are two lists, one by state and one by Company Name)

3. Have you sent Acknowledgement Letters to your suppliers?

- (1) One letter must be in the possession of each supplier for 2 years past the last distribution date.
- (2) Provide one on company letterhead, either in hardcopy or through electronic media, affirming verbatim:
 - (a) that the distributor will not ship such VFD feed to an animal production facility that does not have a VFD;
 - (b) that the distributor will not ship such VFD feed to another distributor without receiving a similar written acknowledgment letter; and
 - (c) that the distributor has complied with the distributor notification requirements. If you issue VFD feed only to a client under a VFD order, you will not need to have an acknowledgement letter.

4. Have you received Acknowledgement letters from all of your customers of VFD feeds?

(1) Only your business customers or animal producer customers that manufacture their own feeds provide acknowledgement letters. Animal producers that do not manufacture their own feeds will utilize VFD documents to purchase feed you manufacture for them.

5. Have you reviewed an example VFD before, to ensure you can identify if it is complete and valid?

- (1) Review FDA's Guidance For Industry #233.
- (2) Guidance For Industry #120 would also be beneficial, although it doesn't contain the samples of VFDs.

6. Are you aware of resources to help you verify the VFD's drug information for validity?

- (1) The drug source label, if a Type A medicated article is the best and easiest resource.
- (2) Animal Drugs @ FDA is an online database that contains summary information for all drug approvals and is keyword searchable. (Google "Animal Drugs @ FDA")
- (3) FDA's website contains blue bird labels that you can reference for drug levels, uses and what the outgoing label to accompany the VFD feed should look like.
- (4) Private industry has created several publications and software systems to assist with drug validation and labeling.

(5) There is also Code of Federal Regulations, etc.,...

7. Have you updated all of your branded (store-brand) and custom-mix feed labeling?

- (1) Use the same resources in item 4 and update them immediately!
- (2) Double check drug levels, indications (uses/purposes), and use directions.
- (3) VFD drug feeds will need to include the VFD statement on the label directly beneath the product name on the principal display of the tag: "Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian."

8. <u>The DATCP templates have changed!! Either request a CD from your inspector or download them from the DATCP website. *ALL* templates are revised – VFD and non-VFD.</u>

9. What will my animal producer customers be required to do?

- (1) They must have a Veterinary Client Patient Relationship (VCPR) established. As per Wis. Stat. §89.02(8), a VCPR means:
 - (a) the vet has assumed responsibility for making medical decisions regarding the health of the animals and the animals' need for medical treatment, and the producer has agreed to accept those decisions and to follow the related instructions;
 - (b) the vet has sufficient knowledge of the animal(s) to make a diagnosis of the medical condition of the animal(s) because the vet has recently examined the animal(s) or has made medically appropriate and timely visits to the location of the animal(s); and
 - (c) the vet is readily available for follow-up treatment of the animal(s) if the animal(s) has an adverse reaction to the vet's treatment.
- (2) They must acquire a complete and valid Veterinary Feed Directive document from a licensed vet prior to requesting you manufacture or distribute a VFD feed for/to them. Yes, unfortunately, this may be a service that costs a fee.
- (3) They must ensure a copy of the VFD document gets to you (either from the vet or from the customer him/herself), and retain a copy for their own records.
- (4) They must work with you and their vet to rework a VFD if the drug information does not fit within the confines of the approval, conditional approval, or index listing.
- (5) They may not feed a VFD feed after the expiration date the vet wrote on the VFD document (you may not manufacture post-expiration either).